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Attorney Docket No.: 3985.240-US

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Havelund et al.

Application No.: 09/398,365

Group Art Unit: 1646

Filed: September 17, 1999

Examiner: C. Saoud

Confirmation No: 9987

For: Acylated Insulin

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with 37 C.F.R. 1.56, 1.97 and 1.98, Applicants submit herewith references which they believe may be material to the patentability of this application and with respect to which there may be a duty to disclose in accordance with 37 C.F.R. 1.56.

While the references may be "material" under 37 C.F.R. 1.56, it is not intended to constitute an admission that the references are "prior art" unless specifically designated as such.

The filing of this Information Disclosure Statement shall not be construed as a representation that no material references other than those listed exist or that a search has been conducted.

The references are listed in Form PTO-1449 which is in accordance with the requirements of M.P.E.P. 609. A copy of the references is also enclosed.

The references are as follows:

1. U.S. Patent 5,646,242
2. U.S. Patent 5,164,366
3. U.S. Patent 5,905,140
4. U.S. Patent 3,869,437

5. GB Patent 1,343,113
6. EP 1 227 107 A1
7. WO 95/07931
8. Lapidot et al., *Journal of Lipid Research*, Vol. 8, pages 142-145, (1967);
9. Asada et al., *Pharmaceutical Research*, Vol. 11, No 8. pages 1115-1120 (1994);
10. Bessellink et al., *Applied Biochemistry and Biotechnology*, Vol. 43, pages 227-246, (1993);
11. Boyd et al., *Int. J. Peptide Protein Res* 4, pages 109-115, (1972);
12. Boyd et al., *Int. J. Peptide Protein Res.* 4, pages 117-122, (1972);
13. Bradbury et al., *Eur. J. Biochem*, vol. 76, pages 573-582, (1977);
14. Brandenburg et al., *Hoppe Seyler's Z. Physiol. Chem.*, Vol. 353, pages 599-616, (1972);
15. Cannan et al., *Ann. N.Y. Acad. Sci.*, Vol. 41, pages 241-266, (1941);
16. Chan et al., *Biochem J.*, Vol. 193, pages 419-425, (1981);
17. Cooper et al., *Proc. Austr. Biochem Soc.*, Vol. 3, page 36, (1970);
18. Eugene Fredericq, *Journal of Polymer Science*, Vol. 12, pages 287-300, (1954);
19. Friesen et al., *Semisynthetic Peptides and Proteins*, Offord & Dibello, pages 161-179, (1977);
20. Friesen, *Insulin Chemistry, Structure and Function of Insulin and Related Hormones, Proceedings of the Second International Insulin Symposium Aachen, Germany, Sep. 4-7, 1979*; Brandenburg and Wollmer, pages 125-133;
21. Geiger et al., *Hoppe Seyler's Z. Physiol. Chem.*, Vol. 352, pages 1487-1490, (1971);
22. Saul Lande, *J. Org Chem.*, Vol. 36, pages 1267-1270, (1971);
23. Lande et al., *Endocrinology*, Vol. 90, pages 597-604, (1972);
24. Leclerc et al., *Can. J. Chem.* Vol 46, pages 1047-1051, (1968);
25. Lindsay et al., *Eur. J. Biochem*, Vol. 15, pages 547-554, (1970);
26. Lindsay et al., *Biochem J.* Vol. 121, pages 737-745, (1972);
27. Massey et al., *Eur. J. Biochem*, Vol. 31, pages 470-473, (1972);
28. May et al., *J. Biol. Chem.*, Vol. 253, pages 686-690;
29. Saunders et al., *FEBS Letters*, Vol. 26, pages 286-288, (1972);
30. Saunders Thesis, pages 63-67, (1974);
31. Saunders et al., *Biochem J.*, Vol 165, pages 479-486, (1977);
32. Schuttler, *Hoppe Seyler's Z. Physiol. Chem.*, Vol. 360, pages 1721-1725, (1979);
33. Sheffer et al., *Can. J. Biochem*, Vol 57, pages 489-496, (1979);
34. Tanford, *J. Am. Chem. Soc.*, Vol 72, pages 441-451, (1950);
35. Tanford, *Adv. Protein Chem.*, Vol. 17, pages 142-144, (1962).

It is respectfully requested that these references be considered by the Patent and Trademark Office in its examination of the above-identified application and be made of

record therein. The Examiner is also invited to contact the undersigned if there are any questions concerning this paper or the attached references.

The information disclosure statement submitted herewith is being filed **within** three months of the filing date of a national application or date of entry into the national stage of an international application or **before** the mailing date of a first Office action on the merits, or **before** the mailing date of a first Office action after the filing of a request for continued examination. Therefore, no fee is due. However, please charge any fees should they be required, to Novo Nordisk Pharmaceuticals, Inc. Deposit Account No. 14-1447.

Respectfully submitted,

Date: September 3, 2003

  
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PATENT TRADEMARK OFFICE



U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		Atty. Docket No. 3985.240-US	Serial No. 09/398,365
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Applicant Havelund et al.	
		Filing Date September 17, 1999	Group 1646

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,646,242					
	5,164,366					
	5,905,140					
	3,869,437					

## FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	1,343,113						
	1 227 107 A1						
	95/07931						

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	1	Lapidot et al., <u>Journal of Lipid Research</u> , Vol. 8, pages 142-145, (1967);
	2	Asada et al., <u>Pharmaceutical Research</u> , Vol. 11, No 8, pages 1115-1120 (1994);
	3	Besselink et al., <u>Applied Biochemistry and Biotechnology</u> , Vol. 43, pages 227-246, (1993);
	4	Boyd et al., <u>Int. J. Peptide Protein Res</u> 4, pages 109-115, (1972);
	5	Boyd et al., <u>Int. J. Peptide Protein Res</u> 4, pages 117-122, (1972);
	6	Bradbury et al., <u>Eur. J. Biochem.</u> vol. 76, pages 573-582, (1977);
	7	Brandenburg et al., <u>Hoppe Seyler's Z. Physiol. Chem.</u> , Vol. 353, pages 599-616, (1972);
	8	Cannan et al., <u>Ann. N.Y. Acad. Sci.</u> , Vol. 41, pages 241-266, (1941);
	9	Chan et al., <u>Biochem J.</u> , Vol. 193, pages 419-425, (1981);
	10	Cooper et al., <u>Proc. Austr. Biochem Soc.</u> , Vol. 3, page 36, (1970);
	11	Eugene Fredericq, <u>Journal of Polymer Science</u> , Vol. 12, pages 287-300, (1954);
	12	Friesen et al., <u>Semisynthetic Peptides and Proteins</u> , Offord & Dibello, pages 161-179, (1977);

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

 FORM PTO-1440 (Rev. 2-32)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Atty. Docket No. 3985.240-US	Serial No. 09/398,365
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		Filing Date September 17, 1999	Group 1646

**U.S. PATENT DOCUMENTS**

## **FOREIGN PATENT DOCUMENTS**

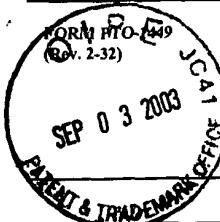
**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

13	Friesen, Insulin Chemistry, Structure and Function of Insulin and Related Hormones, Proceedings of the Second International Insulin Symposium Aachen, Germany, Sep. 4-7, 1979; Brandenburg and Wollmer, pages 125-133;
14	Geiger et al., Hoppe Seyler's Z. Physiol. Chem., Vol. 352, pages 1487-1490, (1971);
15	Saul Lande, J. Org Chem., Vol. 36, pages 1267-1270, (1971);
16	Lande et al., Endocrinology, Vol. 90, pages 597-604, (1972);
17	Leclerc et al., Can. J. Chem. Vol 46, pages 1047-1051, (1968);
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19	Lindsay et al., Biochem J. Vol. 121, pages 737-745, (1972);
20	Massey et al., Eur. J. Biochem, Vol. 31, pages 470-473, (1972);
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22	Saunders et al., FEBS Letters, Vol. 26, pages 286-288, (1972);

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 FORM PTO-1449 (Rev. 2-32)	<b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>	Atty. Docket No. 3985.240-US	Serial No. 09/398,365
	<b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	Applicant <b>Havelund et al.</b>	
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**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

23 24 25 26 27 28	Saunders Thesis, pages 63-67, (1974);
	Saunders et al., Biochem J., Vol 165, pages 479-486, (1977);
	Schuttler, Hoppe Seyler's Z. Physiol. Chem., Vol. 360, pages 1721-1725, (1979);
	Sheffer et al., Can. J. Biochem, Vol 57, pages 489-496, (1979);
	Tanford, J. Am. Chem. Soc., Vol 72, pages 441-451, (1950);
	Tanford, Adv. Protein Chem., Vol. 17, pages 142-144, (1962).

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